action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, this action also does not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

Under RCRA section 3006(b), EPA grants a State's application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective May 24, 2004.

### List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Incorporation-by-reference, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

**Authority:** This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: April 14, 2004.

**Robert E. Roberts,**

*Regional Administrator, Region VIII.*

[FR Doc. 04–9284 Filed 4–22–04; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Medicare & Medicaid Services

## 42 CFR Part 424

**[CMS–1185–F]**

**RIN 0938–AK79**

## Medicare Program; Elimination of Statement of Intent Procedures for Filing Medicare Claims

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule removes the written statement of intent (SOI) procedures, set forth in 42 CFR 424.45, used to extend the time for filing Medicare claims. In the absence of an SOI, providers and suppliers (and, where applicable, beneficiaries) have from 15 to 27 months (depending on the date of service) to file claims with Medicare contractors.

**EFFECTIVE DATE:** This final rule is effective on May 24, 2004.

**FOR FURTHER INFORMATION CONTACT:** David Walczak, (410) 786–4475.

### I. Background

The purpose of the statement of intent (SOI) procedures is to extend the timely filing period for the submission of an initial Medicare claim. An SOI, by itself, does not constitute a claim, but rather is a means of extending the deadline for filing a timely and valid claim. Our regulations at § 424.32, ''Basic requirements for all claims,'' and § 424.44, ''Time limits for filing claims,'' require that Medicare claims be filed on Medicare-designated claims forms by providers, suppliers, and beneficiaries according to Medicare instructions. These claims must be filed by the end of the year following the year in which the services were furnished. Services furnished in the last 3 months of a calendar year are deemed to be furnished in the subsequent calendar year; therefore, a provider, supplier, or beneficiary has until December 31 of the second year following the year in which the services were furnished to file claims. Where an SOI has been filed with the appropriate Medicare contractor and the contractor notifies the submitter of the SOI that the SOI is valid (that is, the SOI sufficiently identifies the beneficiary and the items or services rendered), the period in which to file a claim may be extended an additional 6 months after the month of the contractor's notice.

The original regulation on extending the time to file claims for Medicare benefits at 20 CFR 405.1693, was based on 20 CFR 404.613, which pertained to applications for Social Security benefits. Section 404.613 reflected the Social Security program's interest in allowing virtually any type of writing to be a placeholder for filing a claim for Social Security benefits, provided that a perfected claim was submitted shortly thereafter. We instituted the SOI procedures because we believed that Medicare beneficiaries might sometimes need extra time to file a Part B claim due to extenuating circumstances such as poor health or unfamiliarity with the claims filing process.

However, experience has shown that beneficiaries rarely submit SOIs directly. Medicare contractors that we surveyed reported no SOIs were directly submitted by beneficiaries for the claims filing period ending December 31, 2001, the latest year for which we have complete data. One reason for the lack of beneficiary-initiated SOIs is the fact that beneficiaries rarely need to file claims. The percentage of Part B claims taken on assignment is about 98 percent today, compared to about 52 percent in 1975. (''Assignment'' is the process by which the physician or other supplier agrees to accept Medicare payment in full for a Part B covered item or service and files the claim for the payment.) Even for Part B claims not taken on assignment, the statute now requires the physician or supplier to file the claim and provides for sanctions for failure to do so. (See section 1848(g)(4) of the Social Security Act (the Act)). The number of Part A claims filed by beneficiaries has always been minimal because the statute requires that payment for Part A services generally be made only to providers of services, with very limited exceptions. (See section 1814(a) of the Act). Therefore, we believe that the SOI procedures are no longer necessary because they are not serving their intended purpose.

Further, we believe retention of the SOI procedures is counterproductive because of the amount of resources needed to process SOIs submitted by States and because the SOI procedures may encourage or facilitate inappropriate behavior on the part of some States and some providers.

Each year, our contractors receive an enormous number of SOIs that are submitted by States that, having first made Medicaid payments to dually-eligible (that is, Medicare and Medicaid) beneficiaries, subsequently believe that Medicare should be the proper payor. Subsequent to several court decisions in the early 1990s, we permitted States to ''stand in the shoes'' of a dually-eligible beneficiary for claims filing and appeals. For example, States are not required to obtain a beneficiary's signature to request providers to file a Part A claim or to file an appeal. We also have permitted States and their contractors to file SOIs on the States' behalf or as appointed representatives of the beneficiaries.

The great majority of SOIs are filed on paper and therefore, must be manually processed to determine whether they are valid. According to our requirements, SOIs must contain detailed and specific information to ensure that a subsequently filed claim was in fact protected by an SOI. (See Program Memorandum AB–03–61)). Also, these SOIs are typically filed in large batches near the end of the timely filing period. All of these factors contribute to the amount of resources and consequent cost incurred in processing the SOIs.

We also believe that the SOI procedures may contribute to States ''paying and chasing'' instead of following the required cost-avoidance procedures and to the incorrect submission of claims to Medicaid by providers. Our regulations at § 433.139(b) provide that, unless a waiver is granted under § 433.139(e), a State Medicaid agency that has established the probable existence of third party liability (including Medicare liability) at the time a claim for Medicaid payment is presented to it, must reject the claim and return it to the provider for a determination of liability. This process is known as cost avoidance. Some States, however, have been paying thousands of Medicaid claims, despite the knowledge that the beneficiaries involved are entitled to Medicare. These States subsequently identify a significant portion of the claims that they have paid as ones for which Medicare is the proper payor, and use the SOI procedures to extend the time for providers to file claims.

The fact that large numbers of claims are paid first by Medicaid and then identified as payable by Medicare raises the inference that providers are not as careful as they should be as to which payor they initially submit claims, and that States, by initially paying these claims, are not fully practicing cost avoidance. We are concerned that the availability of the SOI procedures to extend the time for filing claims is contributing to inappropriate behavior. We also note that many of the claims filed with Medicare subsequent to the SOIs are ''demand bills,'' which require full medical review, thus increasing the claims processing cost for our contractors. (Where a provider believes that a service is not covered by Medicare but the beneficiary (or the State as the beneficiary's representative) requests the provider to bill Medicare regardless, the provider's Medicare provider agreement requires it to bill Medicare. This bill is known as a ''demand bill.'' It requires full medical review because the fact that the provider initially believed that the service was not covered by Medicare raises the question of whether Medicare must pay it.)

Moreover, we are aware that providers and suppliers sometimes file SOIs. However, we believe, that the filing periods in § 424.44 (15 to 27 months, depending on the date the service was furnished) are more than an adequate amount of time to submit claims.

The percentage of claims processed and paid compared to the total number of SOI claim requests received was 4.4 percent, based on a survey of SOI requests filed with Medicare contractors for the claims filing period that ended December 31, 2001 (the latest year for which data were available).

The entire SOI claims process is performed manually. The steps in this process are the following:

- Determining if an SOI request is valid or invalid;
- Examining a later-submitted claim to determine whether the claim was protected by the SOI that was submitted earlier; and
- Adjudicating the claim (which, in many cases, involves full medical review).

Based on the survey of SOI claim requests submitted to Medicare contractors for 2001, we have estimated the manual processing of SOI claim requests to cost approximately $12,000,000. (It is noted that this cost estimate may vary from year to year because of the following: (1) The number of SOI claim requests submitted by providers, suppliers and States is not a constant number and varies from year to year; (2) the manual processing costs may vary for each SOI claim request, depending on the size and complexity of the SOI claim request; and, (3) changes in State billing practices may result in fewer submissions of SOI claim requests, if a State chooses to ''cost avoid'' rather than ''pay and chase.'')

It is also noted that the above cost estimate does not include overtime costs and is not inclusive of all SOI claim requests submitted to all Medicare contractors for the claims filing period that ended December 31, 2001. In addition, this cost estimate does not include hearing costs, for example, in the case of a provider or supplier who disagrees with the final claim

determination and files an appeal. As stated, only 4.4 percent of SOI claim requests submitted were actually processed and paid. Therefore, based on the above information, we have concluded that the SOI process is a resource burden on Medicare contractors, providers, and suppliers, with little return or benefit to the States.

This final rule will have little financial impact on entities that currently submit SOI requests. The requirements for submitting a claim are similar to the requirements for submitting a valid SOI claim request. Since an SOI must be filed within the timely filing period, we anticipate no additional burden for these entities to submit claims timely. Therefore, for the above reasons, we are removing § 424.45 from the regulations.

## II. Provisions of the Proposed Regulation

On July 25, 2003 we published a proposal in the **Federal Register** (68 FR 44000) to remove § 424.45. In the absence of § 424.45, providers, suppliers and beneficiaries will still have from 15 to 27 months to submit claims to Medicare.

## III. Analysis of and Responses to Public Comments

We received two timely public comments on the July 25, 2003 proposed rule concerning the removal of the SOI procedures. A summary of the comments and responses follow:

*Comment:* A commenter wrote that the SOI process benefits some physician groups that experience physician turnover. The commenter stated that the physician turnover results in extended delays in obtaining needed documents to complete the CMS–855 enrollment forms. The SOI process has enabled this entity to bill the Medicare program after the timely filing period has expired, for services furnished by physicians who had not completed these forms.

*Response:* We believe that the timely filing period of 15 to 27 months (depending on the date of service) is sufficient time for a physician group to submit the necessary enrollment paperwork and have it processed by Medicare prior to filing a claim. A physician group must have all the necessary provider/supplier enrollment paperwork completed for all of its physicians before the physicians furnish services to Medicare beneficiaries. In any case where this is not feasible, the paperwork must be completed and signed in a reasonable time following the delivery of services. This will allow the physician group to submit the enrollment forms and have them processed prior to the expiration of the timely filing period.

*Comment:* One commenter believes that elimination of the SOI process will simply shift a burden from Medicare contractors to dually-eligible beneficiaries and their providers. The commenter believes that providers will experience cash flow problems if States deny Medicaid payment until after a Medicare demand bill is processed and provided two suggestions to address the concerns. Finally, the commenter asserts that changing the timeframe in which demand bills must be submitted will not reduce the burden on Medicare contractors, because contractors will still need to process demand bills.

The commenter suggested that if the current SOI process is eliminated, then the Medicare regulation on the time limits for filing claims be modified to extend the timely filing period in two instances. First, the time limit for claims that are submitted within the timely filing period but are rejected by Medicare's claims processing system during the last three months of the filing period should automatically be extended for at least an additional three months. Second, if we experience systems problems that prevent claims processing, the timely filing period should be extended for a period equal to the number of days within the timely filing period that we are unable to process a provider's claims (because of the systems problems).

*Response:* We disagree that eliminating the SOI procedures will shift a burden to providers. Instead, we expect that there will be improved efficiencies for States and providers, as well as Medicare contractors, because there will be incentives to bill and pay correctly the first time. One reason for our proposal to eliminate the SOI process is our belief that it may contribute to the inappropriate billing and payment practices of some providers and States concerning claims for dually-eligible beneficiaries. By removing what amounts to an automatic extension of time for States to decide whether a claim that it has paid must be submitted to Medicare, we hope to focus States' and providers' attention on whether a claim must be paid by Medicaid or Medicare in the first instance. We believe that providers will wish to avoid the possibility of having to file a claim with Medicare on short notice because they submitted it to Medicaid inappropriately, and that States will wish to avoid having to notify their Medicaid providers on short notice that they have to submit claims to Medicare. We note that processing written SOIs is a separate process from processing demand bills. Therefore, eliminating the SOI process will, in fact, reduce a resource burden on Medicare contractors.

The timely filing period is 15 to 27 months, depending on the date of service. We believe this already provides sufficient time for providers to submit claims and to correct any problems that cause a rejection of a claim. Providers and suppliers must file claims promptly to allow enough time to correct any claims that may be rejected for technical reasons.

Additionally, current rules already protect providers in potential instances of our systems problems that prevent claims processing. If a claim is submitted timely and there is a delay in our processing of a claim, there is no need for an extension of the timely filing period. If a claim cannot be accepted by us because of a CMS systems problem (and not a systems problem of the provider), then the administrative error provision specified at § 424.44(b) may be applied to extend the timely filing period.

## IV. Provisions of this Final Rule

This final rule incorporates the provisions of the proposed rule by removing the SOI procedures found at § 424.45.

## V. Collection of Information Requirements

This document does not impose new information collection and recordkeeping requirements but does remove an old one.

Removing § 424.45 will reduce costs and workload burdens on providers and suppliers. Specifically, by removing the written SOI procedures, we hope to: (1) Reduce provider, supplier and Medicare contractor resource burdens; (2) reduce the burden placed on providers and suppliers from having to resubmit claims, and also from having to reimburse States for claims that were incorrectly paid for by the States; (3) reduce Medicare contractor administrative costs; (4) eliminate changes to existing intermediary/carrier claims payment systems; (5) encourage States to pursue cost-avoidance procedures to ensure that Medicaid is truly the payor of last resort, and thus reduce the need to use "pay and chase'' procedures; (6) reduce the necessity for medical review at the contractor level; (7) strengthen Medicare and Medicaid program integrity efforts to ensure correct payment the first time; and (8) improve coordination efforts between the Medicare and Medicaid programs.

**VI. Regulatory Impact Statement**

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This is not a major rule. This final rule will have no substantial economic impact on either costs or savings to the Medicare or Medicaid programs.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million annually (see 65 FR 69432). Individuals and States are not included in the definition of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital located outside of a Metropolitan Statistical Area with fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant impact on a substantial number of small entities or rural hospitals because providers and suppliers will still have 15 to 27 months to file claims. Although some providers and suppliers may be small entities or rural hospitals, they are not filing a significant number of SOIs and the information required to file a valid SOI is essentially the same information that providers and suppliers are required to provide when filing a valid claim. We are aware that some States rely on the SOI process at the end of the period for Medicare timely claims filing, to pay and recover expenditures for some of their claims that could have been paid by Medicare. Elimination of the SOI process will require that these States revert to the standard recovery process in the Medicaid regulations to assure that claims are filed within the Medicare timely filing requirements (15 to 27 months). While the elimination of the SOI process will not completely eliminate the issue of ''pay and chase,'' we believe it will encourage States to pursue cost-avoidance procedures to ensure that Medicaid is truly the payer of last resort, reducing the need to use ''pay and chase'' procedures.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule would not have such an effect on State, local, or tribal governments, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a final rule that would impose substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

While this rule will not have a substantial effect on State and local governments, States need to preserve their ability to appropriately recover expenditures for Medicaid benefits that should have been paid by Medicare. We are aware that some States rely on the SOI process, at the end of the period for Medicare timely claims filing, to recover expenditures for some of their claims that could have been paid by Medicare. Elimination of the SOI process will require that these States revert to the standard recovery process in the Medicaid regulations to assure that claims are filed within the Medicare timely filing requirements (15 to 27 months).

For the reasons discussed earlier in this regulation, we believe this timeframe is adequate to address the States' need for recovering claims from Medicare. We will continue to address the States' concerns on these payment and recoupment issues, through the efforts of the State Technical Advisory Group on Third Party Liability, and will continue to consult with States about issues affecting their ability to recover expenditures for some of their claims that should have been covered by Medicare.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects in 42 CFR Part 424**

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

■ For reasons set forth in the Preamble, the Centers for Medicare and Medicaid Services is amending 42 CFR chapter IV as set forth below.

## PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority citation for part 424 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**§ 424.45 [Removed]**

■ 2. Section 424.45 is removed.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 10, 2003.

**Thomas A Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: January 21, 2004.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 04–9316 Filed 4–22–04; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HOMELAND SECURITY

## Federal Emergency Management Agency

## 44 CFR Part 65

**[Docket No. FEMA–D–7555]**

## Changes in Flood Elevation Determinations

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Interim rule.

**SUMMARY:** This interim rule lists communities where modification of the Base (1% annual chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be